

ORGANIZATION  
OF TERATOLOGY  
INFORMATION  
SERVICES

OFFICE: (520) 626-4382  
FAX: (520) 626-5115  
EMAIL: <http://orpheus-1.ucsd.edu/otis>

Ms. Toni Stifano  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fisher Lane Room 1061  
Rockville, MD 20857

SEP -1 A9:19

August 24, 1999

Dear Ms. Stifano:

This letter is written in response to the call for comments on the following **draft** document: "Guidance for Industry: Establishing Pregnancy Registries" docket number 99D-1541.

The Executive Committee of the Organization of Teratology Information Services (OTIS) supports the draft and believes this document should become the standard for investigators studying the effects of environmental exposures and potential risks to the mother and fetus.

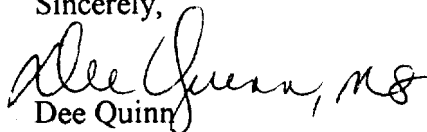
We applaud your efforts to make pregnancy registries more standard and meticulous. This will assist us in providing improved teratogenicity risk assessments and education to the public.

**Omitted, however, is the vital need for long-term follow-up and diagnosis of defects not seen at birth. It is well known that one-half or more of all birth defects are diagnosed after the neonatal period. An example would be third trimester maternal use of streptomycin and hearing loss in children, not usually diagnosed until later.**

With inclusion of long-term follow-up, these documents are not only excellent guidelines for industry, but have the opportunity to become primary "tools" for students, educators and investigators trying to understand the complicated issues of evaluating human studies of pregnancy outcomes.

All involved in creation of these documents are to be commended.

Sincerely,

  
Dee Quinn  
President

Gerald Briggs	Robert Felix	Sandra Gangell	Janine Polifka	Julia Robertson	Lori Wolfe
Member at Large	Secretary	Past President	Member at Large	Member at Large	Treasurer

99D-1541

C7



College of Medicine  
Obstetrics & Gynecology  
PO Box 245078  
Tucson AZ 85724-5078

Ms. Toni Stifano  
Dockets Management Branch (HFA-309)  
Food and Drug Administration  
5630 Fisher Lane Room 1061  
Rockville, MD 20857

Docket 99D-1541